Firm

Individual Signature Date

Mayumi Maeda Reg. No. 40,075

*4 /*2004

PTO/SB/21 (01-03)
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EMPON!	y		Application Number	10/666			
مستن	IRANSWIIIIAL		Filing Date	09/19/2	2003		
	FORM		First Named Inventor	Robert	S. Ga	ılen	
a	to be used for all correspondence after initial	filing)	Art Unit	1743		•	
			Examiner Name	unknow	₩n		
Tc	otal Number of Pages in This Submission	10	Attorney Docket Number	DDI-02	28CON	∛ 1	
		ENC	LOSURES (Check all that	t apply)			
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53		Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Addre Terminal Disclaimer Request for Refund CD, Number of CD(s)			After Allowance Communication to Group Appeal Communication to Board of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Other Enclosure(s): Statement under CFR 1.97	
		1					

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Signature	Jane Sley	Date	10-5-2004				

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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PTO/SB/17 (10-03)

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FEE TRANSMITTAL for FY 2004

(\$) 180

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

Name (Print/Type)

Signature

Mayumi Maeda

Complete if Known					
Application Number	10/666,364	-			
Filing Date	September 19, 2003				
First Named Inventor	Galen				
Examiner Name	Yelena G. Gakh				
Art Unit	1743				
Attorney Docket No.	DDI-0028CON1				

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)							
Check Credit card Money Other None	3. ADDITIONAL FEES							
✓ Deposit Account:	Large Entity Small Entity							
Denosit	Fee Code	Fee (\$)		Fee (\$)	Fee Description	Foo Doid		
Account Number	1051	130	2051	• •	Surcharge - late filing fee or oath	Fee Paid		
Deposit Laboration Control of the Laboration	1052	50	2052		Surcharge - late provisional filing fee or			
Name	1052	120	1052	120	cover sheet Non-English specification			
The Director is authorized to: (check all that apply)	1053 1812	130 2.520	1053 1812		For filing a request for ex parte reexamination			
Charge fee(s) indicated below Credit any overpayments	1804	920*	1804	•	Requesting publication of SIR prior to			
Charge any additional fee(s) or any underpayment of fee(s)					Examiner action			
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action			
FEE CALCULATION	1251	110	2251	55	Extension for reply within first month			
1. BASIC FILING FEE	1252	420	2252	210	Extension for reply within second month			
Large Entity Small Entity	1253	950	2253	475	Extension for reply within third month			
Fee Fee Fee Fee Paid Code (\$) Code (\$)	1254	1,480	2254	740	Extension for reply within fourth month			
1001 770 2001 385 Utility filing fee	1255	2,010	2255	1,005	Extension for reply within fifth month			
1002 340 2002 170 Design filing fee	1401	330	2401	165	Notice of Appeal			
1003 530 2003 265 Plant filing fee	1402	330	2402	165	Filing a brief in support of an appeal			
1004 770 2004 385 Reissue filing fee	1403	290	2403	145	Request for oral hearing			
1005 160 2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to institute a public use proceeding			
. SUBTOTAL (1) (\$)	1452	110	2452	55	Petition to revive - unavoidable			
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1453	1,330	2453	665	Petition to revive - unintentional			
Fee from	1501		2501		Utility issue fee (or reissue)			
Extra Claims below Fee Paid Total Claims -20** = X =	1502	480	2502		Design issue fee			
Independent 311 - 1	1503	640	2503		Plant issue fee			
Claims - 3" =	1460	130	1460		Petitions to the Commissioner			
Large Entity Small Entity	1807	50	1807		Processing fee under 37 CFR 1.17(q)	180		
Fee Fee Fee <u>Fee Description</u>	1806	180	1806		Submission of Information Disclosure Stmt Recording each patent assignment per	-100		
Code (\$) Code (\$) 1202 18 2202 9 Claims in excess of 20	8021	40	8021	40	property (times number of properties)			
1201 86 2201 43 Independent claims in excess of 3	1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))			
1203 290 2203 145 Multiple dependent claim, if not paid	1810	770	2810	385	For each additional invention to be			
1204 86 2204 43 ** Reissue independent claims			20.0	-	examined (37 CFR 1.129(b))			
over original patent	1801	770	2801		Request for Continued Examination (RCE)			
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent	1802	900	1802	900	Request for expedited examination of a design application			
SUBTOTAL (2) (\$)	Other f	٠.						
**or number previously paid, if greater; For Reissues, see above	*Reduc	ced by	Basic F	iling Fe	ee Paid SUBTOTAL (3) (\$) 180			
SUBMITTED BY (Complete (if applicable))								

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40.075

Telephone 408 956 4790

2004

Date





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Robert Galen et al.

Serial No.

10/666,364

Art Unit: 1743

Filed

September 19, 2003

Examiner: Yelena G. Gakh

For

Apparatus for Combined Assay for Current Glucose Level and Intermediate

or Long-Term Glycemic Control

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Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with the first or second After Final Submission, therefore: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in \$1.17(p). In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in §1.17(p). \boxtimes In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

	\boxtimes	Copies	s of each of the references listed on the attached Form PTO-1449 are						
en	closed here	rewith.							
la a		-	s of references listed on the attached Form PTO-1449 are enclosed						
ne	erewith EXC	EPI II	141:						
			In view of the voluminous nature of references, and the likelihood that						
			these references are available to the Examiner in the file history of the						
			parent application (Serial No. 09/477,900), copies are not enclosed						
			herewith.						
		\boxtimes	If any of the foregoing publications are not available to the Examiner,						
	•		Applicant will endeavor to supply copies at the Examiner's request.						
			· · · · · · · · · · · · · · · · · · ·						
		Copies	s of only foreign patent documents and non-patent literature are enclosed						
in	accordance	with 37	CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application						
pu	blication lis	ted on th	he attached Form PTO-1449 are not enclosed because this U.S. patent						
ар	application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement								
na									
·un	der 37 CFR	1.98 (a))(2)(i).						
		There a	are no listed references which are not in the English language.						
as	follows:	The rel	levance of those listed references which are not in the English language is						
	· 🗀	Attache	ed are copies of search report(s) from corresponding patent application(s),						
wh	ப nich are liste		e attached Submission Under MPEP 609 D.						
44.1	11010		attached Cachinoton Chack the Li VV/ D.						

Attached are the following non-published pending patent applications which
may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-
0750/DDI-0028-CON1/MM.
Respectfully submitted,
Mayumi Maeda Reg. No. 40,075
Attorney for Applicants
Johnson & Johnson

Johnson & Johnson International Patent Law Division Attention: Philip Johnson P.O. Box 1222 New Brunswick, NJ 08903 (408) 956-4790

PTC/SB/08A (08-00)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 1 of 1

a conection of information unless it displays	a valid OMB control number.
Application Number	10/666,364
Filing Date	09/12/2003
First Named Inventor	Galen
Group Art Unit	1743
Examiner Name	Yelena G. Gakh
Attorney Docket Number	DDI-028CON1

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item	_
Examiner's	Cite	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	T2
Initials*	No.1	publisher, city and/or country where published	1 '
· · · · · · · · · · · · · · · · · · ·		English Abstract of Japanese Patent JP63182567 published July 27, 1988, Applicant Isolab, Inc.	├──
		English Abstract of Japanese Patent JP5209836 published August 20, 1993, Applicant Terumo Corp.	
		English Abstract of Japanese Patent JP4110662 published April 13, 1992, Applicant Kiyouto Daiichi Kagaku:KK	!
		English Abstract of Japanese Patent JP52131786 published November 4, 1997, Applicant Raydulo Balichi Raydulo Ko.	
		Letter from Shusaku Yamamoto dated September 7, 2004 forwarding Japanese Office Action and Search Results.	ļ
		Letter from Shusaku Yamamoto dated September 7, 2004 forwarding Japanese Office Action and Search Results.	
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Examiner	Date		
Signature	Considered	14.	

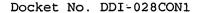
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert Galen et al.

Serial No. : 10/666,364 Art Unit: 1743

Filed : September 19, 2003 Examiner: Yelena G. Gakh

For : Apparatus for Combined Assay for Current Glucose Level

and Intermediate or Long-Term Glycemic Control

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10-5- 2004 (Date of Deposit)

Jane Silarajs
(Name of applicant, assignee, or Registered Representative)

(Signature)

10-5- 2004

(Date of Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

STATEMENT UNDER 37 C.F.R. §1.97(e)

In accordance with 37 C.F.R. §1.97(e), certification is hereby made that:

Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or

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patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Mayumi Maeda Reg. No. 40,075 Attorney for Applicants

Johnson & Johnson
International Patent Law Division
Attention: Philip Johnson
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New Brunswick, NJ 08903
(408) 956-4790
DATED: (9/4/04